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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,674	02/13/2007	Mohammad Djavad Mossalayi	604-790	2319

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
09/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,674	MOSSALAYI ET AL.	
	Examiner	Art Unit	
	PHUONG HUYNH	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,40 and 58-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *59,60 and 64* is/are allowed.

6)☒ Claim(s) *14,40, 58, 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/5/09* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 10, 2010 has been entered.

Claims 14, 40 and 58-64 are pending and being acted upon in this Office Action.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections withdrawn

The objection to Claims 61, 62 and 14 has been obviated by the claims amendment filed March 10, 2010.

Claim Rejections withdrawn

The rejection of claim 63 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been obviated by the claims amendment filed March 10, 2010.

The enablement and written description rejections of claims 14, 40 and 58-64 under 35 U.S.C. 112, first paragraph, have been obviated by the claims amendment filed March 10, 2010.

The rejection of claim 59 under 35 U.S.C. 102(b) as being anticipated by Jouault et al (of record, Glycobiology 11(8): 693-701, 2001; PTO 1449) has been obviated by the claims amendment filed March 10, 2010.

The rejection of claim 59 under 35 U.S.C. 102(b) as being anticipated by JP2002187899 (published July 5, 2002 PTO 1449) has been obviated by the claims amendment filed March 10, 2010. Specifically, the reference does not teach the peptide consisting of the amino acid sequence of SEQ ID NO: 4 or 7.

The rejection of claim 59 under 35 U.S.C. 102(b) as being anticipated by Santamaria et al (Clinical Immunology 101(3): 296-302, 2001; PTO 892) has been obviated by the claims amendment filed March 10, 2010. Specifically, the reference does not teach the peptide consisting of the amino acid sequence of SEQ ID NO: 4 or 7.

The rejection of claims 59 and 64 under 35 U.S.C. 103(a) as being unpatentable over DE19749277 A1 (of record, published May 5, 1999; PTO 1449) or JP2002187899 (of record, published July 5, 2002 PTO 1449) or Santamaria et al (of record, Clinical Immunology 101(3): 296-302, 2001; PTO 892) each in view of Harlow et al (of record, in Antibodies a Laboratory Manual, 1988, Cold Spring harbor laboratory publication, Cold Spring Harbor, NY, page 321-323, PTO 892) has been obviated by the claims amendment filed March 10, 2010.

Claims rejections remain

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by DE19749277 A1 (published May 5, 1999; PTO 1449).

The DE19749277 patent teaches a composition comprising a peptide consisting of the amino acid sequence of FHENWPS and a pharmaceutical acceptable carrier such as PBS (see col. 2, lines 24-33, sequence, claim 4 of the patent, in particular). The reference peptide FHENWPS is 100% identical to the claimed peptide of SEQ ID NO: 1, see claim of the patent, in particular. The term comprising is open-ended. It expands the composition to include additional agent such as albumin or agarose or polyacrylic beads, see abstract, in particular. The reference peptide is useful for affinity purify albumin. Given the reference peptide FHENWPS has the same structure as that claimed peptide; the reference peptide inherently binds to CD23 at least about 10^{-6} M. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure or sequence, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Thus, the reference teachings anticipate the claimed invention.

Applicants' arguments filed March 10, 2010 have been fully considered but are not found persuasive.

Applicants' position is that DE19749277 relates to chromatographic reagents useful for separation of albumin from biological fluids by affinity chromatography. The FHENWPS peptide is attached to a carrier material such as agarose. The only reference to PBS (column 2, lines 24-33) is for washing the agarose. Thus, DE19749277 does not disclose a pharmaceutical composition or a pharmaceutically acceptable carrier. Therefore, the anticipation rejection over DEt9749277 is moot.

Contrary to applicants' assertion that that the DE19749277 does not teach pharmaceutical acceptable carrier, the reference PBS is a pharmaceutical acceptable carrier, and when combine with the reference peptide FHENWPS, it forms a pharmaceutical composition. The term "comprising" is open-ended. It expands the claimed composition to include additional agent such as agarose. Given the claimed peptide has the same amino acid sequence as that of the reference peptide, if the claimed peptide binds to CD23, so does the reference peptide. Further, a product is a product, irrespective of its intended use. Note, amending the claims to recite a method of treating inflammatory rheumatoid arthritis comprising administering a composition comprising at least one CD23-binding peptide consisting of the amino acid sequence of SEQ ID NO: 1 and a pharmaceutical acceptable carrier may obviate this rejection since none of the cited references of record teach such method. However, Applicant is reminded that since applicant has received an action on the merits for the originally presented invention, new claims drawn to such method will be withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE19749277 A1 (published May 5, 1999; PTO 1449) in view of US Pat No 5,028,592 (of record, issued July 2, 1991; PTO 892).

The teachings of DE19749277 A1 have been discussed supra.

The invention in claims 60 and 61 differs from the teachings of the reference only in that the peptide wherein the N-terminus is acylated.

The invention in claims 60 ad 62 differs from the teachings of the reference only in that the peptide wherein the N-terminus is acetylated.

The invention in claims 60 and 63 differs from the teachings of the reference only in that the peptide wherein the C-terminus is amidated.

The '592 patent teaches protective groups such as acyl or acetyl group bound to the amino terminus or the amidated group to the C-terminus of any bioactive peptide to reduce the susceptibility of the peptide to acid or enzymatic hydrolysis (see col. 4, lines 50-66, in particular). The '592 patent teaches protected peptides are more active pharmacologically than the unprotected peptide (see col. 4, lines 65-66, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a protective group such as acyl or acetyl group bound to the amino terminus of any peptide and/or the amidated group to the C-terminus of any peptide as taught by the '592 patent to any peptide consisting of the amino acid sequence FHENWPS as taught by the DE19749277 A1.

One having ordinary skill in the art would have been motivated to do so because the protective groups would reduce susceptibility of the peptide to acid or enzymatic hydrolysis and the protected peptide is more active pharmacologically than the unprotected peptide as taught by the '592 patent (see col. 4, lines 50-66, in particular). From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Given the examination guidelines for determining obviousness under 35 U.S.C. 103 in view of the Supreme Court decision in *KSR International Co. V. Teleflex Inc. 82 USPQ2d 1385 (2007)* and the Examination Guidelines set forth in the Federal Register (Vol. 72, No. 195, October 10, 2007) and incorporated recently into the MPEP (Revision 6, September 2007), the following rationales to support rejection under 35 U.S.C. 103(a) are noted:

A) Combining prior art elements according known methods to yield predictable results.

B) Use of known technique to improve similar products in the same way.

C) "Obvious to try" --- choosing form a finite number of identified, predictable solutions, with a reasonable expectation of success.

D) Some teachings, suggestion, or motivation in the prior art that would lead to one of ordinary skill to modify the prior art reference to arrive at the claimed invention.

Since reducing enzymatic hydrolysis or peptide in vivo is desirable and have been predictable at the time the invention was made, there would have been reasonable expectation of success in combine the references teachings to arrive at the claimed invention. An obviousness is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See *KSR International Co. V. Teleflex Inc. 82 USPQ2d 1385 (2007).* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Applicants' arguments filed March 10, 2010 have been fully considered but are not found persuasive.

Applicants' position is that none of cited documents discloses or suggests CD23 binding peptides of SEQ ID NO: 2-10, 31, 32, 34, 35, 40, 43 and 53-64; Based on this, the skilled person, as of the filing date of the present application, would have not have envisaged the binding affinities of the peptides described for CD23 molecule, nor the pharmacological activity of the FHENWPS peptide, based on the cited references, taken singly or in combination.

It is clear, therefore that the claimed peptides d SEQ ID NO: 2-10, 31, 32, 34, 35, 40, 43 and 53-6I and a pharmaceutical composition comprising the peptide of SEQ ID NO:: 1, are not anticipated by, or rendered unpatentable in view of; the cited combination of references. Withdrawal of the obviousness rejections is respectfully requested.

US 5,028,592, Hock et at. and Harlow et at. have been cited to support the notion that modifying a peptide by adding acyl, acetyl or amidated groups (US 5,028,592), using D-isomers of amino :acids (Hock *eta,.'.)* or labeling a peptide (Harlow et al*)* is an obvious approach, This is not correct.

The relevant inquiry is would the skilled person, as of the filing date of the present application, have had a reasonable expectation that the peptide of SEQ ID NO: 1 would bind CD23 and have utility in treating rheumatoid arthritis. None of the above mentioned documents describes a peptide binding to CD23, or a peptide having activity on inhibition of NOS production.

In response, the argument with respect to peptides of SEQ ID NO: 2-10, 31, 32, 34, 35, 40, 43 and 53-61 is moot since the rejection with respect to said peptides in claims 59-60 and 64 has been withdrawn.

With respect to the argument that the skilled person, as of the filing date of the present application, would have not have envisaged the binding affinities of the peptides described for CD23, it is noted that the specification as of the filing date of the present application has not determined the binding affinities of any of the claimed peptides, let alone at least about 10^{-6} M. Given the claimed peptide FHENWPS has the same amino acid sequence of that of the reference peptide, if applicant's peptide binds to CD23 of at least about 10^{-6} M, so does the reference peptide.

With respect to the argument that none of the above mentioned documents describes a peptide having activity on inhibition of NOS production, it is noted that none of the rejected claims recites a method of treating rheumatoid arthritis or inhibits iNOS production as argued.

With respect to the argument that none of the above mentioned documents describes a peptide that binds to CD23, as stated earlier, the claimed peptide FHGNWPS has the same amino acid sequence as that of the reference peptide, if the claimed peptide binds to CD23, so does the reference peptide. None of the claims are drawn to a method of treating or inhibiting iNOS using the specific peptide.

Claims 14 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE19749277 A1 (of record, published May 5, 1999; PTO 1449) in view of Heck et al (of record, Proc Natl Acad Sci 93:4036-4039, April 1996; PTO 892).

The teachings of DE19749277 A1 have been discussed supra.

The invention in claim 58 differs from the teachings of the reference only in that the peptide has at least one amino acid which is a D-isomer instead of naturally occurring L-isomer.

Heck et al teach in recent years, a growing number of synthetic peptides containing D-amino acids to capitalize on the residues' ability to provide improved protease stability (pharmacokinetic profile) of the bioactive peptides (see page 4039, col. 2, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to improve the stability of the peptide of Jouault et al by substituting the natural occurring L-amino acid in the peptide of Jouault et al for the D-amino acid isomer as taught by Heck et al.

One having ordinary skill in the art would have been motivated to do so because Heck et al teach it is conventional at the time the invention was made to synthesize peptides containing D-amino acids to

capitalize on the residues' ability to provide improved protease stability (pharmacokinetic profile), alter tertiary structure and affect activity of the bioactive peptides (see page 4039, col. 2, in particular).

Applicants' arguments filed March 10, 2010 have been fully considered but are not found persuasive.

Applicants' position is that none of cited documents discloses or suggests CD23 binding peptides of SEQ ID NO: 2-10, 31, 32, 34, 35, 40, 43 and 53-64; Based on this, the skilled person, as of the filing date of the present application, would have not have envisaged the binding affinities of the peptides described for CD23 molecule, nor the pharmacological activity of the FHENWPS peptide, based on the cited references, taken singly or in combination.

It is clear, therefore that the claimed peptides d SEQ ID NO: 2-10, 31, 32, 34, 35, 40, 43 and 53-6I and a pharmaceutical composition comprising the peptide of SEQ ID NO:: 1, are not anticipated by, or rendered unpatentable in view of; the cited combination of references. Withdrawal of the obviousness rejections is respectfully requested.

US 5,028,592, Hock et at. and Harlow et at. have been cited to support the notion that modifying a peptide by adding acyl, acetyl or amidated groups (US 5,028,592), using D-isomers of amino :acids (Hock *et al.)* or labeling a peptide (Harlow et al*)* is an obvious approach, This is not correct.

The relevant inquiry is would the skilled person, as of the filing date of the present application, have had a reasonable expectation that the peptide of SEQ ID NO: 1 would bind CD23 and have utility in treating rheumatoid arthritis. None of the above mentioned documents describes a peptide binding to CD23, or a peptide having activity on inhibition of NOS production.

The arguments have been addressed above and are incorporated here by reference.

New Ground of Rejection

Claim rejections under - 35 U.S.C. 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is New Matter**.

The recitation of "*about* 10^{-6} M" in claim 40 has no support in the claims and the specification as originally filed. The specification asserts the peptide has a specific binding activity to CD23 of less than 10^{-6} Kd or **between 10^{-6} and 11^{-11} M**, see page 13, line 13.

Claim 59-60 and 64 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9: 00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The IFW official Fax number is (571) 273-8300.

Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/

Primary Examiner, Art Unit 1644

September 24, 2010